K100442

SECTION 5:

510(k) SUMMARY

SEP 7 2010

Submitter: Surgical Innovations plc.
Clayton Wood House
6 Clayton Wood Bank
Leeds
LS16 6QZ
United Kingdom

Tel.: +44 113 230-7597
Fax: +44 113 230-7598

Contact Person: Mike White
Product Development Director

Date Summary Prepared: 10 February 2010

Trade Name: FastClamp Endoscopic Clamping System

Common Name: Endoscope and accessories

Classification Name: Laparoscope, General and Plastic Surgery
(21 CFR 876.1500, Product Code GCJ)

Equivalent to: Laparoscopic Retractors- Cardinal Health, Inc. (K092684)

FISSO Holding System - Baitella AG (K070509).

Mediflex Flex Arm Systems - Mediflex surgical products (pre-amendments device).

Thompson Retractor - Thompson Surgical Instruments, Inc. (pre-amendments device).

Device Description: The FastClamp Endoscopic Clamping System is a non sterile, reusable, laparoscopic clamp instrument. It comprises a table clamp to securely attach to the operating table accessory rail, and an instrument clamp to lock the instrument in place once the instrument has been positioned.

Intended Use: The FastClamp Endoscopic Clamping System is indicated for use in laparoscopic procedures for the surgeon to clamp endoscopic instruments in a fixed position for a period of time.

Substantial Equivalence: Determination of substantial equivalence for the FastClamp Endoscopic Clamping System was based on comparison to the predicate devices in terms of intended use and device technological characteristics, such as design features, materials of composition, principle of operation and presentation. The FastClamp Endoscopic Clamping System is substantially equivalent to the Laparoscopic Retractors in terms of their intended use. The FastClamp Endoscopic Clamping System is substantially equivalent to the FISSO Holding System, MediFlex Flex Arm Systems, and Thompson Retractor in terms of the intended use, design features, material, sterilization, principle of operation and presentation.

Nonclinical tests summary

1. Bench Testing

FastClamp Jaw capability testing

For this test the input criteria was determined to be:

- 5mm (between Ø4.2- Ø7.4) and 10mm (Ø9.2- Ø11.4) nominal test bars remain static between the jaws when a load of 1kg is applied.
- 5mm and 10mm nominal test bars (between Ø4.2- Ø7.4 and Ø9.2- Ø11.4) are positioned in appropriate recess in the jaws and the locking mechanism can be deployed.

The pass results in TN100346 (Exhibit 6) show that the FastClamp Endoscopic Clamping system passes the input criteria, capable of accommodating a range of instruments between Ø4.2- Ø7.4 and Ø9.2- Ø11.4 , and gripping them to withstand a load of 1kg.

Fast Clamp bed frame fixation testing

For this test the input criteria was determined to be:

- FastClamp Endoscopic clamping system is attached to the bed rail over drape; it does not move when a load of 10kg is applied to front, back and both sides.

The pass results in TN100346 (Exhibit 6) show that the FastClamp Endoscopic Clamping system passes the input criteria to withstand a load of 10kg applied to front, back and both sides. It provides an extremely strong and stable instrument platform once it has been correctly adjusted, and locked into position.

Recommended loadings for FastClamp Endoscopic Clamping System

For this test the input criteria was determined to be:

- The FastClamp Endoscopic Clamping System is capable of holding the liver retractor and supporting simulated liver weight of 4kg.

The pass results in TN100384 show that FastClamp Endoscopic Clamping system passes the input criteria: capable of holding a liver retractor in a static position during retraction of simulated liver weights up to 4kg which is double the weight of the average male adult liver.

Packaging drop testing

For this test the input criteria was determined to be:

- Pass in accordance with pass criteria ASTM D4169-1996. After 100% inspection of product after dropping from a height of 610mm, there should be no visible defects found in the product.

The pass results in TN100372 (Exhibit 7) show that the FastClamp Endoscopic Clamping System passes the input criteria where the packaging remained in one piece and the product was not damaged in any way.

2. FastClamp Justification of 2 year useable lifespan

For this test the input criteria was determined to be:

- The FastClamp Endoscopic Clamping System is capable of passing 200 full clean, wash and autoclave cycles, and still functions safely and correctly.

The pass results in TN100362 (Exhibit 10) show that FastClamp Endoscopic Clamping system passes the input criteria, capable of functioning safely after 200 full clean, wash and autoclave cycles. The cosmetic change in color is due to the temperature during autoclaving, and once the change has occurred, there is no evidence of deterioration in the properties of function of the plating.

3. FastClamp steam sterilization validation

The steam sterilization process used for FastClamp Endoscopic Clamping System has been validated in accordance with ISO 17665 Sterilization of health care products – Moist heat.
The results showed that the sterilization requirement has been satisfied in accordance with ISO17665. FastClamp Endoscopic Clamping System Instruction for Use (IFU) has been updated to reflect the sterilization parameters which are 135°C for 30 minutes using gravity displacement with 90 minutes minimum dry time.

The full report of this testing is provided in TN100420.

4. Materials Biocompatibility

From ISO 10993-1:2002, FastClamp Endoscopic Clamping System is an external communicating device with duration < 24 hours, therefore initial tests for consideration are:

1. Cytotoxicity
2. Sensitization
3. Intracutaneous reactivity.

In order to minimize animal tests, an extractivity test was conducted to determine the necessity for sensitization and intracutaneous reactivity.

1. Cytotoxicity Test

The result has showed that the extract of the negative control (polypropylene filters) was non-cytotoxic to L929 cells under the conditions of this test.

The extract of the positive control (rubber bands) was cytotoxic to L929 cells under the conditions of this test.

The extract of the test material was non-cytotoxic.

The full report of this testing (ref. TN 100359) is provided in Exhibit 9.

2. Extractivity Testing

The gravimetric and visual results show that no significant levels of extractable material were found. As such it is considered that the ISO 10993-10 skin irritation and skin sensitization tests should not be conducted. The justification for this is that if no measureable levels of extractable material are produced then it would only be the extractant that is being assessed.

The full report of this testing (ref. TN 100359) is provided in Exhibit 9

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Surgical Innovations plc.
% Mr. Mike White
Product Development Director
Clayton Wood House
6 Clayton Wood Bank
Leeds, LS16 6QZ United Kingdom

SEP 7 2010

Re: K100442
Trade/Device Name: FastClamp Endoscopic Clamping System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: July 12, 2010
Received: July 14, 2010

Dear Mr. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

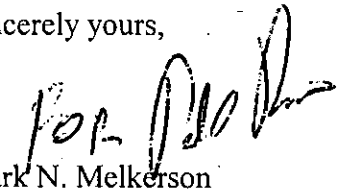
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4:

SEP 7 2010

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): Not known

Device Name: FastClamp Endoscopic Clamping System

Indications for Use: Use in laparoscopic procedures for the surgeon to clamp endoscopic instruments in a fixed position for a period of time.

Prescription Use__X__ AND/ OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Neil R. Ogden for mxn
Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100442